



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d16796

DEC 19 1996

Food and Drug Administration  
2098 Galther Road  
Rockville MD 20850

**WARNING LETTER**

J. Mason Hurt, O.D.  
Mid-South PCM™ Group, P.C.  
2865 Summer Oaks Drive  
Bartlett, Tennessee 38134

Re: Contact Lenses/  
Precise Corneal Molding™ (PCM™)  
Procedure

Dear Dr. Hurt:

The Food and Drug Administration (FDA), Center for Devices and Radiological Health has reviewed promotional and advertising material for the Precise Corneal Molding™(PCM™) System, an "orthokeratology" procedure, in which contact lenses, which you refer to as "molds", are worn during waking hours as well as overnight to reshape the cornea to ultimately correct vision deficiencies without the need for corrective lenses. These lenses are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Contact lenses intended for extended wear (i.e. to be worn overnight) are Class III devices, (See Title 21 of the Code of Federal Regulations (CFR) § 886.5916. They require an approved application for premarket approval (PMA) to support the safety and efficacy of the device prior to commercial marketing and use.

The contact lenses (or "molds") used in your Precise Corneal Molding™ (PCM™) procedure are adulterated within the meaning of section 501(f)(1)(C) of the Act in that they are Class III devices under section 520(l), and do not have an approved application for premarket approval in effect pursuant to section 515.

You should take prompt action to correct this violation. Continued distribution of the device may result in regulatory action by the FDA without further notice. These actions include, but are not limited to, injunction, seizure, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

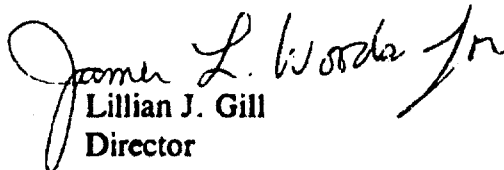
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Please reply to this office, in writing, within 15 working days of receipt of this letter, describing the specific steps you have taken to correct the noted violations including steps taken to prevent the recurrence of similar violations. If the violations cannot be corrected within the 15 days, explain the reason and provide a time line specifying the time within which corrective action will be completed.

A copy of this letter is being sent to the responsible FDA District Office. Please send a copy of your response to the District Director, Nashville District, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217. We request that any action being taken to remove this product from the market be reported to the above mentioned District Office.

Your response to this letter should be sent to the attention of Ms. Veronika J. Fabritzky, Dental, ENT and Ophthalmic Branch, HFZ-331, at the letterhead address.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health